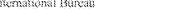
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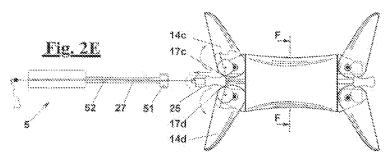
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(54) Time: INTERSPINOUS VERTEBRAL DISTRACTOR FOR PERCUTANEOUS IMPLANTATION



(57) Abstract: Interspinious distractor for percutaneous implantation comprising a central body (10) and two complex of stabilizers (14a, 14b, 14c, 14d), hinged at the end of the body (10) in order to mate from a closed position, which assists the percutaneous implantation of the distractor, to a spread apart position, which limits its movement stabilizing it in the interspinous gap. Means are provided for causing the rotation of the stabilizers that can be operated percutaneously, in particular, by means of can shaped elements sliding axially and adapted to engage a cam-shaped surface, or by a system of the members, and special tools. With respect to the known distractors it can implanted end extracted percutaneously and in a much easier way.

TITLE

INTERSPINOUS VERTEBRAL DISTRACTOR FOR PERCUTANEOUS

IMPLANTATION

DESCRIPTION

Field of the invention

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The present invention relates to an interspinous

vertebral distractor adapted to percutaneous implantation

indifferently from a right or left direction with respect

to the interspinous gap.

Background of the invention

Intervertebral distractors are devices adapted to space two adjacent vertebrae. In particular, the distractors according to the present invention are prostheses conceived for being steadily implanted in the space set between the spinous processes of two adjacent vertebrae, in order to maintain an intervertebral distraction adapted to limit the loads transmitted between the vertebrae in case of degenerative diseases of the intervertebral disc, thus limiting the associated painful effects.

With respect to other vertebral prostheses, the interspinous distractors can be easily implanted, owing to

the relative easy steps with which the spinous processes of two adjacent vertebrae can be slightly spread apart. For the same reasons, such distractors do not jeopardize the local mobility of the spine when bending, and reduce hyperextension. Notwithstanding such advantages, known stabilization problems exist. In other words, an interspinous distractor has to be kept in position, in particular it has to be constrained with respect to movements such that affect its functionality or causing it to in particular, exit from the interspinous gap, with movements in a plane orthogonal to the spine.

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In particular, W02006102269 describes interspinous distractors for keeping the implant within the interspinous gap, comprising a central portion adapted to be contained in the interspinous gap providing an interspinous support adapted to maintain a desired distraction, and stop members consisting of two ends portions, of which one fixed and one mobile; the latter comprises elements movable according to two extreme positions. The fixed end has a profile and a size such that it can be approached laterally against the spinous processes of the two adjacent vertebrae. Adjusting means are provided for the mobile end on which the surgeon acts once implanted the device, creating a bilateral limitation to sliding for the distractor according to its

own longitudinal axis. The interspinous and the supraspinous ligament assist the implant to settle between the spinous processes, in particular with respect to movements in a plane orthogonal to the spine, thus ensuring a local mobility of the spine.

Such device is not however adapted to a percutaneous implantation, owing to an excessive size of the fixed portion of the stop members, influencing the overall size of the distractor, and also because the means for adjusting the movable part of the stop members cannot be operated percutaneously.

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A device is also known, called Synthes®, comprising a central body with substantially cylindrical shape and two couples of movable and reversible stop members that project from the central body, such that the radial size of the device. in closed position, does not exceed eris substantially cylindrical body. Once located endoscopically the body between the spinous processes, the surgeon acts always percutaneously on position adjusting elements of said mobile stop members, causing it to partially exit from the body through suitable slits, the stop members being conformed to hook the spinous processes. Even in this case, the ligament interspinous assists settling the prosthesis between the spinous processes.

The mobile stop members, however, being housed in the cylindrical body, have to rotate in order to protrude from the respective slit. This needs a high internal mechanical complexity. Furthermore, the stop members have a portion remaining in the cylindrical body that is large enough to support the part protruding from the body, in order to assure enough blocking force to the distractor. The presence of the stop members and of the relative mechanisms in the cylindrical body does not allow having distractors under a certain size.

Examples of interspinous distractors, in particular, studied for cervical vertebrae, are disclosed in US20060271049A1, US2007010813A1 and in US US2008108990A1. These distractors have a body from which a wing extends, which can move from a closed position, which does not exceed the height of the body, to a spread apart position that protrudes laterally with respect to the body and can then keep the body settled between two spinous processes, in order to carry out the distraction and at the same time blocking an accidental movement of the body.

Summary of the invention

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It is therefore a feature of the present invention to provide an intervertebral distractor of interspinous type that comprises effective stop members of the body within

the interspinous gap and at the same time allows a percutaneous implantation.

It is also a feature of the present invention to provide an intervertebral distractor of interspinous type that can be blocked in a position steady from both the body ends without the introduction elements of locking fixed by the outside.

It is then a feature of the present invention to provide an intervertebral distractor of interspinous type, adapted to percutaneous implantation, which is of much easier construction than the distractors of the prior art, in particular concerning the stop members.

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It is yet a feature of the present invention to provide an intervertebral distractor of interspinous type, adapted to percutaneous implantation, which is suitable in particular, for vertebrae of the zone lumbar-sacral zone of the spine.

It is a further feature of the present invention to provide an intervertebral distractor of interspinous type, adapted to percutaneous implantation, which has a small size, particularly adapted to the introduction in interspinous spaces different from the lumbar region and to treat patients of low size, typically children.

It is also a feature of the present invention to

provide an interspinous distractor, adapted to percutaneous implantation, and also adapted to percutaneous extraction, with relevant advantages for the patients where the distractor is mounted momentarily in case of disc compressions awaiting permanent treatments.

It is another feature of the present invention to provide an intervertebral distractor of interspinous type, in particular, for introduction between spinous processes of lumbar vertebrae, where the loads necessary for distraction are the highest.

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It is still another feature of the present invention to provide an interspinous distractor which allows, without substantial structural changes, an implantation both in young patients and in elder patients, and for different degrees of disc degeneration.

It is still another feature of the present invention to provide an interspinous distractor adapted to be implanted in patients suffering from scoliosis or other deformations of the spine.

- These and other objects are achieved by an interspinous implant whose characteristic is that it comprises:
 - an elongated body with a first and a second end and a predetermined transversal dimension, adapted to provide an

interspinous support between two adjacent spinous processes, said body having a longitudinal axis;

respectively connected to said first and second ends of said elongated body, said stabilizers being adapted to rotate from a closed position, in which they form a pointed extension of said elongated body, assisting a percutaneous implantation of said distractor, and a spread apart position, wherein said stabilizers in use limit the movement of said distractor, providing a barrier adapted to contain between them said spinous processes;

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- means that can be operated percutaneously movable along said axis and associated with said elongated body and said stabilizers, for bringing said stabilizers from said closed position to said spread apart position or viceversa,
- pivot points distant from said axis, said stabilizers having with respect to said body a distal end and a proximal end, such that said means that can be operated percutaneously moving along said axis acts on said stabilizers for causing both said first and said second couple of stabilizers to rotate about said pivot points so that said distal end moves from said closed position to

said spread apart position and said proximal end is kept closed to said axis.

The possibility of adjusting percutaneously position of the two stabilizers, from a closed introduction position to a spread apart stabilization position, allows at the same time to implant easily the device and to settle it in the interspinous gap, by mini-invasive implantation steps.

In particular, the position of the stabilizers can be changed with continuity, avoiding lateral backlash of the ()) distractor without forcing too much the stabilizers against the spinous processes. Furthermore, it is possible to ensure that the stabilizers achieve a blocking position, since the stabilizers can be blocked in any desired position.

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Advantageously, the means that can be operated percutaneously cause in the direction of approach a not simultaneous opening movement of the stabilizers with respect to the spinous processes, with advantages for operator that need not use imaging systems, for example with sonographic probes, for checking the relative position of the implant with respect to the spinous processes. In particular, it is possible to open firstly the distal stabilizers with respect to the hands of the surgeon, then

they are caused to touch the spinous processes in said spread apart position with a backward movement, and then the proximal stabilizers can be opened. Furthermore, this opening succession allows carrying out easily the distraction in the presence of angular deformity, scoliosis, ossified tissues on the spinous processes that normally hamper the introduction with the known systems.

In a particular advantageous exemplary embodiment, at least one couple of said stabilizers can rotate about said pivot point beyond said spread apart position continuing further for angles larger than 90°, in particular, between 120° and 180°. This way, is allows a percutaneous extraction is permitted, preventing the ends of the stabilizers to block the extraction. In particular, the two stabilizers that can rotate about said pivot point beyond said spread apart position continuing further for angles larger than 90° have a curved shape with concavity such that during the introduction it is oriented opposite to the axis of the body, and during the extraction it is oriented towards the axis of the body.

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Advantageously, the elongated body has transversal sections substantially elliptical, with longer axis lying in use in a plane substantially orthogonal to the spine.

Furthermore, the elongated body can have a conical

shape, preferably with a cone angle of 4-5°, which can be used advantageously in treating scoliosis. In this case, the larger diameter of the frustoconical is arranged on the side of the concavity of the deformity of the spine.

Advantageously, the interspinous distractor has a first and a second lateral stabilizer that are arranged in use below the median horizontal plane of the body of the distractor, and that are shorter than a corresponding third and fourth stabilizers arranged in use above the median plane. In this way interferences are avoided with the vertebra just below the two distracted vertebras, for example in the presence of scoliosis or other vertebral degenerations.

Furthermore, advantageously, each lateral stabilizer is asymmetrical in a vertical plane; this way possible interference is avoided with the lateral processes of the adjacent vertebrae of the spine.

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Advantageously, said stabilizers are enclosed laterally between fixed protection shells. This way, is obtained a "torpedo-like" profile of the distractor, which assists a percutaneous implantation and extraction.

The means that can be operated percutaneously, in a first exemplary embodiment, comprises a rod slidingly arranged in a longitudinal recess of the elongated body,

said rod having at one end a cam-shaped portion adapted to be put in a space comprised within the stabilizers of the first couple, such stabilizers having each a cam-shaped surface at said proximal end with respect to the body, adapted to engage with a cam-shaped portion of the rod so that a translation of the rod causes a rotation of the lateral stabilizers.

In particular, said proximal end has a convex shape, and said cam-shaped portion of the rod has a corresponding concave shape, whereby said convex shape and concave shape form two conjugate profiles.

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Alternatively, said conjugate profiles of said proximal end and of said cam-shaped portion of the rod are convex, and have on the surface gear-like portions.

Advantageously, the rod has a gripping end opposite to the cam-shaped portion, and this gripping end is adapted to be manoeuvred percutaneously with a first tool.

Preferably, the gripping end is adapted to engage with a spanner-like portion of the tool, this gripping end being selected from the group comprised of:

- a female end for a respective male spanner-like portion,
- a male end for a respective female spanner-like portion.

Advantageously, the means that can be operated percutaneously comprises a cam shaped element adapted to be housed in a space comprised within the stabilizers of the second couple and to be manoeuvred with a second tool, and the cam-shaped element is engageable and lockable on a portion of the rod opposite to the cam-shaped portion, in order to cause a rotation of the stabilizers of the second couple from the closed position to the spread apart position.

In particular, the portion of the rod opposite to the cam-shaped portion has a threaded portion and the cam-shaped element is a cam-shaped nut adapted to be screwed on said threaded portion to cause a rotation of the stabilizers of the second couple from the closed position to the spread apart position or vice-versa.

Preferably, the second tool has a spanner-like portion adapted to engage with the cam-shaped nut.

Advantageously, the intervertebral distractor comprises means for guiding the cam-shaped element and the tool towards the distraction body arranged in an intervertebral interspinous gap.

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In particular, said means for guiding can comprise a wire, and the rod has an axial hole from which the wire extends, whereby the cam-shaped element and the tool are

guided along the axis of the rod by the wire.

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Preferably, the axial hole of the rod is a through hole and the wire is adapted to guide the prosthesis towards the interspinous gap. In particular, it is possible to use a K wire, known also as Kirschner wire, which, as well known, is sufficiently stiff for such a use.

Advantageously, a tubular guide is provided having at the end means for releasably engaging the intervertebral distractor, said tool being in use guided towards the gripping end of the rod and towards the nut through said tubular guide.

Preferably, the engagement means between distractor and tubular guide comprises a couple of teeth arranged at one end of the tubular guide, adapted to engage with corresponding holes provided in said distractor.

Advantageously, for extracting the distractor percutaneously, a tool is provided adapted to engage with the head of the screw for rotating it, which is associated with a device adapted to keep the nut still. In particular, the device adapted to keep the nut still has a plurality of arms telescopically protruding from the tool adapted to engage with the head of the screw, said arms being suitable to form a gripper that grips the head of the screw.

In a second exemplary embodiment of the invention, the

means that can be operated percutaneously comprises:

- a flexible tie member fixed to the stabilizers of at least one of said couples of stabilizers, so that such stabilizers are brought from the closed position to the spread apart position by pulling the tie member,
- means for blocking the flexible tie member when the stabilizers have achieved the spread apart position.

Advantageously, said means for blocking the flexible tie member are reversible, in order to be released for bringing the stabilizers from the actual spread apart position to the closed position for extracting the implant.

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In particular, the means for blocking the flexible tie member comprises a couple of counter rotating friction wheels or circular sectors arranged about respective axes substantially perpendicular to a direction defined by the stretched flexible tie member, such wheels or circular sectors being such that they keep an interference position owing to the mutually friction exerted and with the flexible tie member arranged between them.

As it is apparent from the above, and as it is much clearer from the description of the preferred exemplary embodiments, the stop members have limited mechanical complexity and are easy to manufacture, improving the distractors of the prior art.

The distractor according to the invention may have a nominal size selected from the group comprised of: 8, 10, 12, 14 mm, thus being adapted to a percutaneous implantation.

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Preferably, the elongated body and the stabilizers are made of a metal material, in particular, titanium or titanium alloy. Advantageously, then, the elongated body and the stabilizers have a outer coating surface of a material based on a thermoplastic polymer, which is chosen according to the disc degeneration degree of the vertebra supported by the distractor. In particular, for a slight degeneration degree, in particular, for second or third disc degeneration degrees according to the Pfirman classification, soft materials are more suitable, with reference to the spinous apophysis characteristics, whereas if the degeneration is much more serious (fourth or fifth disc degeneration degrees) a harder material is indicated, having i.e. a modulus of elasticity close to that of the bones concerned with the implant. In particular, the material with modulus of elasticity close to that of the bones can be selected from the group comprised of: polyaryletherketones, known for good biocompatibility characteristics. In particular, the polymer can polyetheretherketone, known commercially also as PEEK®.

An example of softer material, adapted to treat the less serious degenerations, can be instead selected among the polyurethane foams. Such coating material assists moreover the introduction of the distractor between the spinous processes and limits the even unlikely possibility of mechanical local overloads on the spinous processes.

Brief description of the drawings

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The invention will be made clearer with the following description of an exemplary embodiment thereof, exemplifying but not limitative, with reference to the attached drawings wherein:

- Fig. 1A is a perspective view of a first interspinous distractor according to the invention, where the stabilizers of both couples of stabilizers are in closed position;
- Fig. 1B is a perspective view of an elongated body comprised in the distractor of Fig. 1A;
- Fig. 1C is a perspective view of a second embodiment of an interspinous distractor according to the invention, where the stabilizers of both the couples of stabilizers are in open position;
- Fig. 2A is an elevational partially cross sectional side view of an interspinous distractor according to the invention, where the position of the stabilizers is changed

by means of cam-shaped elements adapted to be housed in a space between the stabilizers;

- Fig. 28 shows a rod present in the distractor of Fig. 2A;
- Fig. 20 shows the distractor of Fig. 2A after variation
- s of the position of the stabilizers of the first couple by means of a tool;
 - Fig. 2D shows means operated percutaneously for adjusting the position of the stabilizers of the second couple, comprising a cam-shaped nut adapted to be screwed on a screw threaded portion of said rod and one tool adapted to engage this nut, as well as guiding means to wire and for tool;
 - Fig. 2E shows the distractor of Fig. 2A after variation of the position of the stabilizers of the second couple by means of said nut and said tool;
 - Fig. 2F shows the median cross sectional view F-F of the elongated body of the distractor shown in Fig. 2E;
 - Fig. 2G is a view of a cam-shaped nut;

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- Fig. 3A shows a portion of lumbar vertebrae, where the 20 distractor can be inserted according to the invention;
 - Figs. from 3B to 3D show the steps of introducing the distractor according to the invention;
 - Fig. 4A shows a tubular guide and an embracing portion thereof on the body of the distractor;

- Figs. 4B and 4C show two steps of interaction of the tubular guide with the rod, in the exemplary embodiment of Figs. 2A-2G;
- Fig. 5A is an elevational side view of an intervertebral distractor of interspinous type according to the invention, where the position of the stabilizers is changed by means of flexible tie members connected to them;
 - Fig. 5B shows the distractor of Fig. 5A after variation of the position of the stabilizers of the first couple by means of traction of a first flexible tie member;

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- Fig. 5C shows a wire pulling member, consisting of a couple of friction wheels;
- Fig. 5D shows the distractor of Fig. 5B after opening also of the stabilizers of the second couple by means of traction of a second flexible tie member, the two flexible tie members being pulled by the member of Fig. 5C;
- Fig. 5E shows the median cross sectional view E-E of the elongated body of the distractor shown in Fig. 5D;
- Fig. 6A shows the exemplary embodiment of the distractor of Fig. 5A, where the stabilizers that are arranged in use below to a median horizontal plane of the body of the prosthesis are shorter than the stabilizers arranged in use said above plane;
 - Fig. 6B shows the distractor of Fig. 6A after variation

- of the position of the stabilizers of the first couple by means of traction of a first flexible tie member;
- Fig. 6C shows a wire pulling member, consisting of a couple of friction wheels;
- Fig. 6D shows the distractor of Fig. 6B after opening also of the stabilizers of the second couple by means of traction of a second flexible tie member, the two flexible tie members being pulled by the device shown More in detail, in Fig. 6C;
- 10 Fig. 6E shows the median cross sectional view E-E of a distractor according to the exemplary embodiment of the distractor of Fig. 6A, where furthermore the stabilizers are asymmetrical, and arranged asymmetrically with respect to the diametrical vertical plane of the body of the distractor;
 - Fig. 6F shows the median cross sectional view E-E of a distractor according to the exemplary embodiment of the distractor of Fig. 6A, wherein furthermore, the stabilizers are symmetrical with respect to a longitudinal median plane, and are arranged asymmetrically with respect to the diametrical vertical plane of the body of the distractor;

- Fig. 7 shows the device of Fig. 6A-F arranged between the spinous apophysis of two adjacent vertebrae 67 and 68;
- Fig. 8A is a cross sectional view of an interspinous

distractor according to the invention, where the position of the stabilizers is changed by means of cam-shaped elements adapted to be housed in a space between the stabilizers;

- 5 Fig. 8B shows a rod comprised in the distractor of Fig. 8A;
 - Fig. 8C shows the distractor of Fig. 8A after variation of the position of the stabilizers of the first couple by means of a tool similar to that shown in Fig. 2B;
- Fig. 8D shows a cam-shaped nut for adjusting the position of the stabilizers of the second couple, said nut being adapted to be screwed on a screw threaded portion of said rod shown in Fig. 2B and to be manoeuvred by a tool shown in Fig. 2D and in Fig. 10;
- of the position of the stabilizers of the second couple by means of said nut and said tool;
 - Fig. 8F shows a median cross sectional view F-F of the elongated body of the distractor shown in Fig. 8E;
- 20 Fig. 8G shows the distractor of Figs. 8 A-C-E where the position of the stabilizers of the second couple has been changed in a backward position to assist percutaneous extraction;
 - Fig. 9 shows the distractor of Figs. 8 A-G and one tool

for bringing said stabilizers of said second couple from the spread apart position of Fig. 8E to the backward position of Fig. 8G;

- Fig. 10 shows a tool that engages the nut of Fig. 8D of the tool of Figs. 8A-G for moving said stabilizers of said second couple from said closed position to a spread apart anatomic position, said position being chosen giving to said stabilizers an desired opening angle;
- Fig. 11 shows a detail a type of alternative conjugate

 10 profile adapted to provide the rotation of two stabilizers

 of the distractor of Figs. 8A-G;
 - Fig. 12 is a cross sectional view of a distractor having a different shape of the central body, and stabilizers that can be operated with mechanisms similar to the distractor of Figs. 8A-G;

Description of preferred exemplary embodiments

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With reference to Figs. 1A and 1B a first interspinous vertebral distractor 100 is described comprising an elongated body 10 and two ends 11 and 12 at which two couples of stabilizers 14a-b and 14c-d are connected by two supports 33 and two couples of hinges 13. Each stabilizer 14a-d has internally a slot that houses a portion of the corresponding support 33, with shape such that it allows a rotation about the corresponding hinge 13. In particular,

the hinges 13 are distant from the longitudinal axis 1 and each stabilizer 14a-d has with respect to body 10 a distal end and a proximal end. This way, it is possible to insert the implant percutaneously, in the way hereinafter described in the various exemplary embodiments, moving along the axis 1, acting on the proximal end for causing stabilizers 14a-b and 14c-d to rotate about said pivot points 13.

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In Fig. 1A distractor 100 is shown with both couples of stabilizers 14a-b and 14c-d in closed position, in which configuration distractor 100 is ready for a percutaneous implantation within the spinous processes of two adjacent vertebrae. Fig. 1B shows instead elongated body 10 of the distractor alone.

A second embodiment of an interspinous distractor 800, shown in Fig. 1C, has still an elongated body 10 similar to the elongated body of distractor 100, whereas each couple of stabilizers 84a-b and 84c-d is enclosed between two fixed shells 49; furthermore, stabilizers 84a and 84b, in open position, have a convex face oriented opposite to body 10; in particular, stabilizers 84b and 84d, that are arranged in use below a plane perpendicular to the spine, are shorter than stabilizers 84a and 84d, as described hereinafter.

Figs. 2A-2G show an exemplary embodiment of the distractor indicated as 200, in which a rod 20 is present that can slide in a longitudinal recess 15 of elongated body 10, having transversal sections substantially homothetic to the median cross section shown in Fig. 2F. At one end of the rod 20, shown in detail in Fig. 2B, a cam-shaped portion is visible 21, adapted to engage with the surfaces eccentric or cam-shaped 17a-b of stabilizers 14a-b causing a rotation thereof. The opposite end 22 is instead conformed in order to be manceuvred with a tool 4, for example with a hexagonal head 41, or a screw driver end. During this translation, rod 20 engages also the recesses 16 and 18, which are made respectively between the two stabilizers 14c-d and 14a-b.

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By this manoeuvre, rod 20 can translate from the actual position shown in Fig. 2A to the position shown in Fig. 2C, and stabilizers 14a-b rotate about portions 43 running from the closed position to the spread apart position, whereas stabilizers 14c-d remain still in closed position. This is advantageous in use since a surgeon can choose a second moment for blocking the distractor in position, while stabilizers 14a-b abut against the spinous seeking the better position for body 10.

A portion 23 of rod 20 close to end 22 (Fig. 28) has a

threaded portion 23 on which a nut 25 (Fig. 2G) of the distractor can be screwed. This nut 25 has a through hole 27a, and a cam-shaped surface 26, adapted to engage with the cam surfaces 17c-d of stabilizers 14c-d, causing a rotation thereof.

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Nut 25 is manoeuvred by a tool 5 that has an hexagonal female head 51 adapted to engage with cam-shaped nut 25 (Fig. 2D and 2E).

By this manoeuvre, the nut 25 moves to the position shown in Fig. 2E and stabilizers 14c-d rotate running from the closed position of Fig. 2C to the spread apart position of Fig. 2E.

Example a Kirschner wire or K wire, passing in rod 20 through end 22 and recess 29 (Fig. 2F). When arranging the distractor in the interspinous gap, the wire 27 extends rigidly in the patient, thus allowing the introduction in a first phase of tool 4 and in a second phase of tool 5. This way, tools 4 and 5 can be guided towards distraction body 1 to the interspinous position. To allow the movement of the wire 27, the tools 4 and 5 have recesses 42 and 52 (Fig. 2C and 2E). Obviously, the introduction can be made also without quiding means 27.

In the various exemplary embodiments of the distractor

as described in the present application, stabilizers 14a-d are advantageously made of titanium and the central body 10 has a core 8 of titanium and a coating surface 3, for example of a polyetheretherketone (FEEK®); this is shown in the median cross sectional view of Fig. 2F, according to plane F-F whose shape is shown in Fig. 2E; in this cross section central recess 15 and rod 20 with recess 29 are also shown. Alternatively, the coating surface 3 can be made of a soft material, for example polyurethane foam, according to the disc degeneration degree of the patient.

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In Figs. 3A-C it is shown in more detail how the device 200 as described can be guided towards the interspinous gap 69 set between the spinous apophysis 67 and 68 of two adjacent vertebrae, by means of a Kirschner wire 27. To this end, as already said above, rod 20 (Fig. 2B) is open axially. Furthermore, for locating the distractor in the interspinous gap a tubular guide can be provided 8a, shown in detail in Fig. 4A. It has at one end a couple of gripping teeth 81 adapted to engage with conjugate holes 82 arranged within the longitudinal recess 16 of stabilizers 14c and 14d. The tubular guide has a inner recess such that it allows the movement of the tools 4 and 5 of Fig. 2C and 2E, as shown respectively in Figs. 4B and 4C, for opening said couples of stabilizers, orderly, 14a-b and 14c-d;

Figs. 5A-D show again the interspinous distractor 100 1A, where the means which can be operated of Fig. percutaneously for adjusting the position of stabilizers 14a-b and 14c-d comprises flexible tie members or wires 6 and 7. In particular, flexible tie member 6 has two ends 61a and 61b fixed to stabilizers 14a-b, in this case through two hinges 13; a rod 19 is also provided guiding two branches of flexible tie member 6 towards the two stabilizers 14a-b. Flexible tie member 6 comes out from distractor 1 running through the longitudinal recess 15 of elongated body 10 and through recess 16 determined between the two stabilizers 14c-d; an end 62 of flexible tie member 6, opposite to ends 61a-b, remains out from the body of the patient. In a same way, a flexible tie member 7 has two ends 71c-d fixed to stabilizers 14c-d by two hinges 13 and a rod 19; this flexible tie member comes out from distractor 1 running also through the recess 16; an end 72, opposite to ends 71c-d remains out from the body of the patient. A traction on the flexible tie members 6 and 7, effected from an endoscopic position, allows bringing respectively stabilizers 14a-b and 14c-d from the closed position shown in Fig. 5A to the spread apart position shown in Fig. 5D.

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Once brought the stabilizers of the two couples to the

respective spread apart positions, the two flexible tie members 6 and 7 act as guiding means for a device 30 for blocking the stabilizers in the spread apart position; this device has a couple of friction counter rotating wheels 31 and a tool 9 is used comprising a recess 91 and a head 92 adapted to arrange the device 30 to a contrast with support 33. Traction on wires 6 and 7 forces the device 30 in this position, owing to the friction exerted with and between friction wheels 31.

Alternatively, or in addition to the friction wheels, circular sectors can be provided opposite and gear-like, kept in blocked position with the locked wires within them. As further alternative, or in addition, the wires can be locked with rings of a metal material, for example of titanium, sliding along the wire and then locked on the wire with plastic deformation, in order to avoid a back sliding of the wire.

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Also in this case, the central body and the stabilizers have a core of titanium, with a coating surface 3 of polyetheretherketone (PEEK®), as shown in Fig. 5E, which is a cross sectional view of elongated body 10 according to plane E-E, whose shape is indicated in Fig. 5D, where central recess 15 and flexible tie member 6 are also shown.

Similarly, the operation of distractor 600 shown in

Figs. 6A-D provides the same concepts. This distractor differs from distractor 100 of Figs. 5A-D since stabilizers 14b and 14d, which are arranged in use below the median horizontal plane of body 10 of the distractor, are shorter than the corresponding stabilizers 14a and 14c, as shown, in particular, in Figs. 6A and 6B; this arrangement is used to avoid interference with the spinous processes or lateral processes of the vertebra just below the two distracted vertebrae, which can occur, in particular, when there are case of scoliosis. vertebral degenerations or in Furthermore, device 600 has stabilizers 64a-d that are asymmetrical with respect to a desired vertical plane; such stabilizers can be conceptually obtained cross-sectioning corresponding stabilizers of the type 14a-d, symmetrical, with a vertical plane parallel to the axis of distractor, and removing one of the two parts of each lateral stabilizer thus obtained, typically the part of smaller size. This is used for avoiding an interference with the lateral processes, as shown in Fig. Alternatively, to what shown in Fig. 6D, Fig. 6E represents a solution with stabilizers that are symmetrical with respect to the own longitudinal median plane, but arranged asymmetrically with respect to the vertical median plane of the body of the distractor.

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The distractor 800 shown in Figs. 8A-E, as well as in Fig. 1C, has the two couples of stabilizers 84a-b and 84c-d enclosed between fixed protection shells 49. The opening/closing movement of the stabilizers is effected by translating a rod 70 (Fig. 8B) with a cam shaped end 77, and a nut 75 with a cam-shaped surface 76 (Fig. 8D), said translation being operated by a tool in a similar way as described for distractor 200 of Figs. 2A-G.

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In this device an anatomic solution is used that provides lower stabilizers 84b and 84d of length lower than the higher stabilizers 84a and 84c. Like in the exemplary embodiments described previously, the concave part of the stabilizers of the couple 84a-b is oriented, in open position, opposite to the central body 10, the stabilizers of this couple being adapted to rotate from the closed position of Fig. 8A to the spread apart position of Fig. 8C and 8D, and eventually to the closed position shown in Fig. 8G. This is used to assist a percutaneous extraction of the distractor from the interspinous gap, said extraction occurring according to the direction 89 of the arrow shown in Fig. 8G.

Concerning the stabilizers of the couple 84c-d, their convex part is oriented, in the spread apart position, opposite to the central body. Furthermore, stabilizers 84c-

d are capable of rotating about the pivot point 83 beyond said spread apart position continuing further for angles larger than 90°, in particular, between 120° and 180°, and in Fig. 8G of about 150°. As shown in Fig. 8G the two stabilizers 84c-d have a curved shape with concavity such that during the introduction according to arrow 88 (Fig. 8A) it is priented opposite to the axis 1 of the body, and during the extraction according to arrow 89 (Fig. 8G) it is oriented according to the same side of the axis 1 of the body. Then, the stabilizers of this couple 84c-d can rotate from the closed position of Fig. 8A to the spread apart position of Fig. 8C and 8D, up to reaching the closed position shown in Fig. 8G. In the latter closed position, stabilizers 84c-d have a rotation induced by the same extraction, once the cams 84c and 84d have abandoned the cam-shaped portion 76 of the cam-shaped nut 75. particular, the opposite concavity of stabilizers 84c-d is used to assist the percutaneous extraction of the distractor from the interspinous gap according to the direction 89. With a numbering similar to that relative to distractor 200, in Figs. 8A-G the other elements of the distractor 800 are described.

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As shown in Fig. 9, for adjusting the opening angle of a distal couple of stabilizers 84c-d by rod 70, a tool 90

can be used having a couple of symmetrical tools 96 engageable with two horizontal pins 99 integral to a fixed portion of the distractor 800, for example with protective shells 49, such tools being adapted to block nut 75 in a determined position; tool 90 comprises, furthermore, a rotatable device 94 with an hexagonal female head adapted to engage with the male head of rod 70; with a rotation of the tool it is therefore possible to move rod 70, causing a translation associated with the rotation, suitable for moving stabilizers 84c-d with micrometric precision and according to reproducible positions.

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With reference to Fig. 10, the proximal end of stabilizers 84c and 84d have a convex shape, which can be a cam-like shape 87c and 87d, whereas the cam-shaped portion 76 of the rod has a corresponding concave shape, whereby said convex and concave shapes form two conjugate profiles. This allows a micrometric adjustment of stabilizers 84c and 84d.

An alternative exemplary embodiment that can be applied to any embodiments of the invention is shown in Fig. 11, and provides conjugate profiles 130c-d of the proximal end and of the cam-shaped portion 120 of the rod that are convex, and may have on the surface gear-like portions (not shown).

In Fig. 12 is shown, according to another exemplary embodiment of the invention, a distractor 900 having central body 110 with the shape of a right circular frustum of cone, with the generatrix at an angle with respect to the axis according to an angle 113 of 5°. Like the central body 10 of the device 800 of Figs. 8A-G, it has a coating 108 of a material chosen according to the disc degeneration degree of the patient, and a inner core 103 of titanium. To provide the shape frustum-conic of the central body 110, the core 108 has an end 104 having size larger of the end 105, as well as stabilizers 114a/b larger than stabilizers 114c/d. The distractor 900 can be used advantageously for patients suffering from scoliosis. In this case, the part of stabilizer corresponding to end 104 is located according to the part of the spine that has a concavity. In analogy to distractor 800, distractor 900 has its lower stabilizers 114b and 114d having a length lower than the higher stabilizers of a same couple, respectively 114a and 114c, and this is an anatomic solution that makes the distractor 900 also suitable for treating patients suffering from scolicsis. The position of stabilizers 114a-d is adjusted acting on movable components of the distractor 900 similar to those of the distractor 800, in particular, stabilizers 114a and 114d are brought from a closed position to a

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spread spart position and vice-versa by translating a rod lil similar to rod 70 of Fig. 8B, whereas stabilizers 114b and 114c are moved by nut 112 similar to nut 75 of Fig. 8D, owing to the cam surfaces of the rod and of the nut adapted to engage, respectively, the couples of cam surfaces of stabilizers 114a-d and 114c-d.

Obviously, the solution of Fig. 12 can be applied to any desired type of interspinous distractor.

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The foregoing description of a specific embodiment will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt for various applications such an embodiment without further research and without parting from the invention, and it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiment. The means and the materials to realise the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

CLAIMS

1. Intervertebral distractor of interspinous type characterised in that it comprises:

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- an elongated body with a first and a second end and a predetermined transversal dimension, adapted to provide an interspinous support between two adjacent spinous processes, said body having a longitudinal axis;
- a first and a second couple of mobile stabilizers, connected respectively to said first and second ends of said elongated body, said stabilizers being adapted to rotate from a closed position, in which they form a pointed extension of said elongated body, assisting a percutaneous implantation of said distractor, to a spread apart position, where said stabilizers in use limit the movement of said distractor, providing a barrier adapted to contain between them said spinous processes;
- means that can be operated percutaneously movable along said axis and associated with said elongated body and said stabilizers, for bringing said stabilizers from said closed position to said spread apart position or vice-yersa,

- said stabilizers being connected to said ends of said body at pivot points distant from said axis, said stabilizers having with respect to said body a distal end and a proximal end, such that said means that can be operated percutaneously moving along said axis acts on said stabilizers, for causing both said first and said second couple of stabilizers to rotate about said pivot points, such that said distal end moves from said closed position to said spread apart position and said proximal end is maintained close to said axis.

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- 2. Intervertebral distractor according to claim 1, wherein said means that can be operated percutaneously cause a variation with continuity of the position of said lateral stabilizers.
- 3. Intervertebral distractor according to claim 1, wherein said means that can be operated percutaneously cause in an introduction direction a not simultaneous opening movement of the stabilizers with respect to the spinous processes.
- 20 4. Intervertebral distractor according to claim 1, wherein at least one couple of said stabilizers can rotate about said pivot point beyond said spread apart position continuing further for angles larger than 90°, in particular, between 120° and 180°.

5. Intervertebral distractor according to claim 4, wherein said couple of said stabilizers that can rotate about said pivot point beyond said spread apart position continuing further for angles larger than 90° have a curved shape with concavity such that during the introduction it is oriented opposite to the axis of the body, and during the extraction it is oriented towards the axis of the body.

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- 6. Intervertebral distractor according to claim 1, wherein said elongated body has transversal sections substantially elliptical, with longer axis lying in use in a plane substantially orthogonal to the spine.
 - 7. Intervertebral distractor according to claim 1, wherein said elongated body has a frustoconical shape, in particular, with an angle of $4-5^{\circ}$.
 - 8. Intervertebral distractor according to claim 1, wherein a first and a second lateral stabilizers are provided arranged in use below the median horizontal plane of the body of the distractor that are shorter than a corresponding third and fourth stabilizers arranged in use above the median plane.
 - 9. Intervertebral distractor according to claim 1, wherein said lateral stabilizers are asymmetrical in a vertical plane, unbalanced in a direction opposite to the

lateral processes.

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- 10. Intervertebral distractor according to claim 1, wherein said stabilizers are enclosed laterally between fixed protection shells, said shells having a pointed profile such that resistance is reduced during an percutaneous introduction or extraction.
- 11. Intervertebral distractor according to claim 1, wherein said means that can be operated percutaneously comprises a rod slidingly arranged in a longitudinal recess of the elongated body, said rod having at one end a cam-shaped portion adapted to be put in a space comprised within the stabilizers of the first couple, such stabilizers having each a cam-shaped surface at said proximal end with respect to the body, adapted to engage with the cam-shaped portion of the rod such that a translation of the rod causes a rotation of the lateral stabilizers.
 - 12. Intervertebral distractor according to claim 11, wherein said proximal end has a convex shape, and said cam-shaped portion of the rod has a corresponding concave shape, whereby said convex shape and concave shape form two conjugate profiles.
 - 13. Intervertebral distractor according to claim 12, wherein said conjugate profiles of said proximal end

- and of said cam-shaped portion of the rod are convex, and have on the surface gear-like portions.
- 14. Intervertebral distractor according to claim 11, wherein said rod has a gripping end opposite to the cam-shaped portion, and this gripping end is adapted to be manogured percutaneously with a first tool.

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- 15. Intervertebral distractor according to claim 14, wherein said gripping end is adapted to engage with a spanner-like portion of the tool, this gripping end being selected from the group comprised of:
 - a female end for a respective male spanner-like portion,
 - a male end for a respective female spanner-like portion.
- 15 16. Intervertebral distractor according to claim 11, wherein said means that can be operated percutaneously comprises a cam shaped element adapted to be housed in a space comprised within the stabilizers of the second couple and to be manoeuvred with a second tool, and the cam-shaped element is engageable and lockable on a portion of the rod opposite to the cam-shaped portion, in order to cause a rotation of the stabilizers of the second couple from the closed position to the spread apart position.

- 17. Intervertebral distractor according to claim 16, wherein said portion of the rod opposite to the camshaped portion has a threaded portion and the camshaped element is a cam-shaped nut adapted to be screwed on said threaded portion to cause a rotation of the stabilizers of the second couple from the closed position to the spread apart position or vice-versa.
- 18. Intervertebral distractor according to claim 16, wherein said second tool has a spanner-like portion adapted to engage with the cam-shaped nut.

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- 19. Intervertebral distractor according to claim 11, wherein said intervertebral distractor comprises means for guiding the cam-shaped element and the tool towards the distraction body arranged in an intervertebral interspinous gap.
- 20. Intervertebral distractor according to claim 18, wherein said means for guiding comprises a wire, and the rod has an axial hole from which the wire extends, whereby the cam-shaped element and the tool are guided along the axis of the rod by the wire.
- 21. Intervertebral distractor according to claim 11, wherein a tubular guide is provided having at the end means for releasably engaging the intervertebral distractor, said tool being in use guided towards the

gripping end of the rod and towards the nut through said tubular quide.

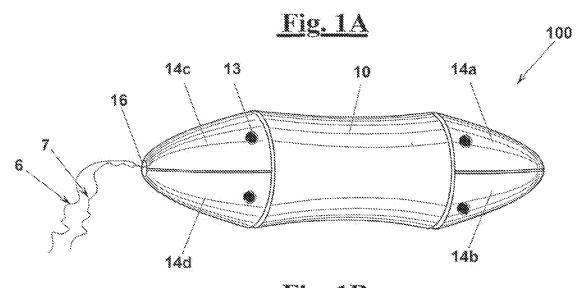
- 22. Intervertebral distractor according to claim 11, wherein for extracting the distractor percutaneously, a tool is provided adapted to engage with the head of the screw for rotating it associated with a device adapted to keep the nut still, said device adapted to keep the nut still having in particular a plurality of arms telescopically protruding from the tool adapted to engage with the head of the screw, said arms being suitable to form a gripper that grips the head of the screw.
 - 23. Intervertebral distractor according to claim 1, wherein said means that can be operated percutaneously comprises:

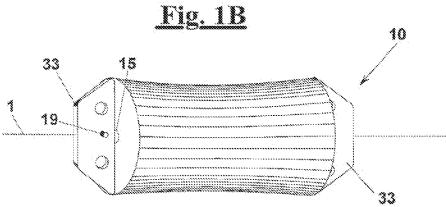
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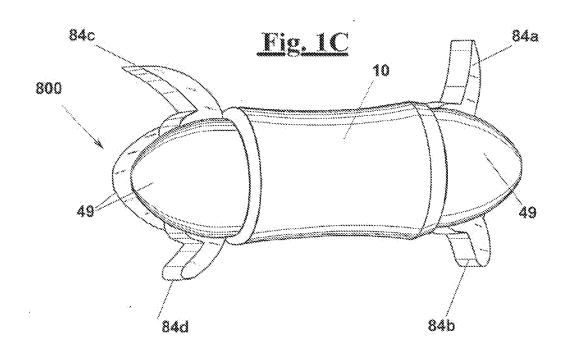
- -a flexible tie member fixed to the stabilizers of at least one of said couples of stabilizers, such that such stabilizers are brought from the closed position to the spread apart position by pulling the tie member, -means for blocking the flexible tie member when the stabilizers have achieved the spread apart position.
- 24. Intervertebral distractor according to claim 23, wherein said means for blocking the flexible tie member are reversible, in order to be released for bringing

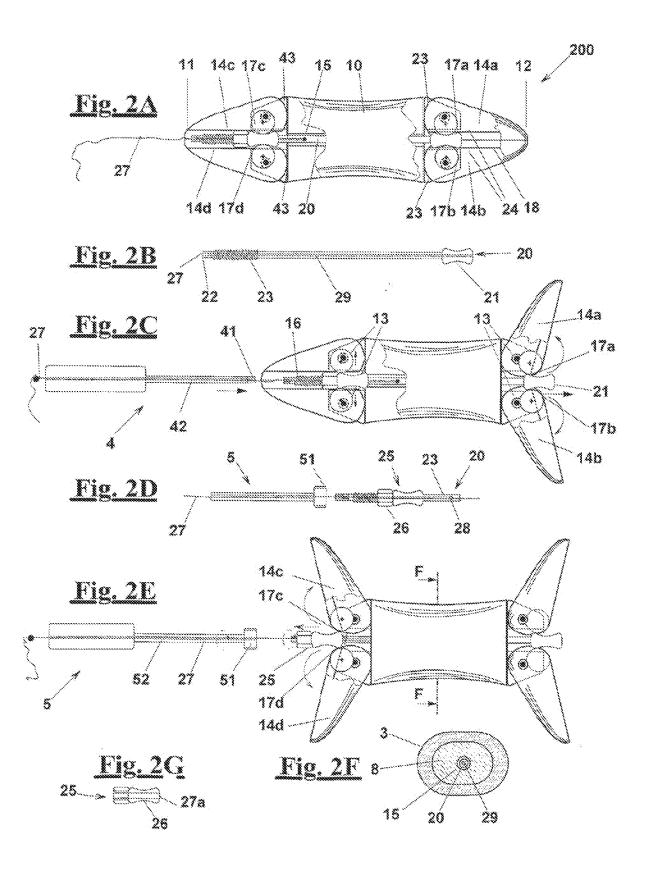
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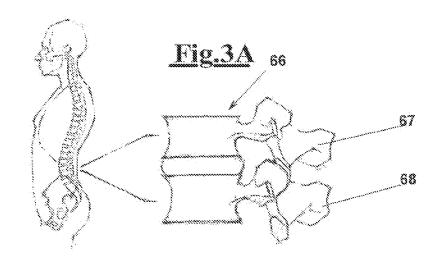
- the stabilizers from the actual spread apart position to the closed position for extracting the implant.
- 25. Intervertebral distractor according to claim 23, wherein said means for blocking the flexible tie member comprises a couple of counter rotating friction wheels or circular sectors arranged about respective axes substantially perpendicular to a direction defined by the stretched flexible tie member, such wheels or circular sectors being such that they keep an interference position owing to the mutually friction exerted and with the flexible tie member arranged between them.

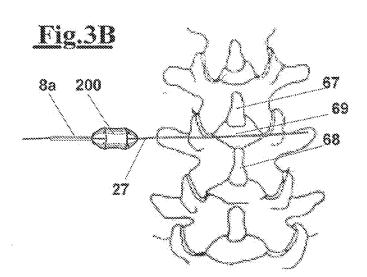


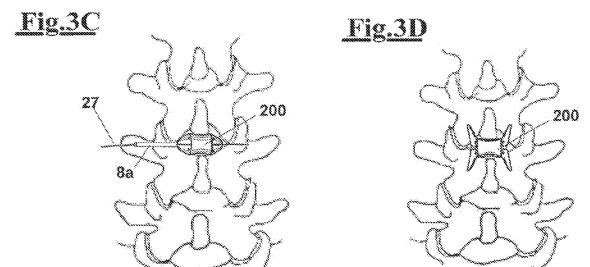


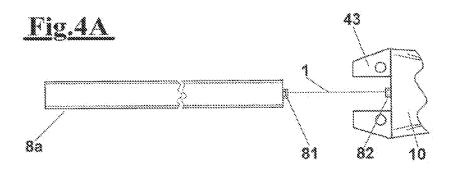


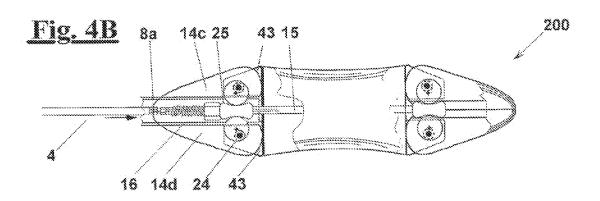


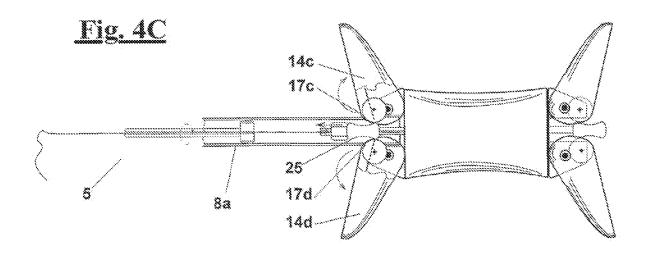


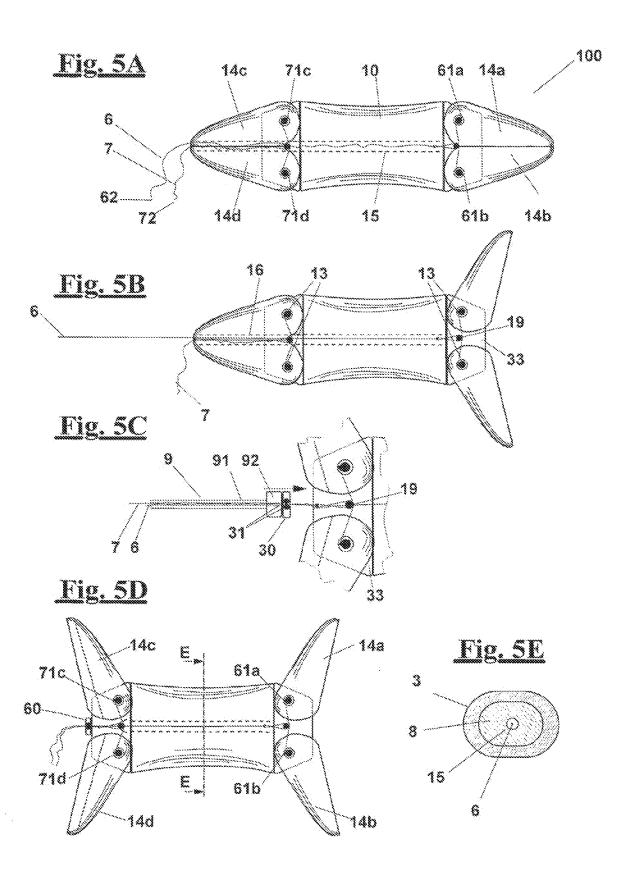


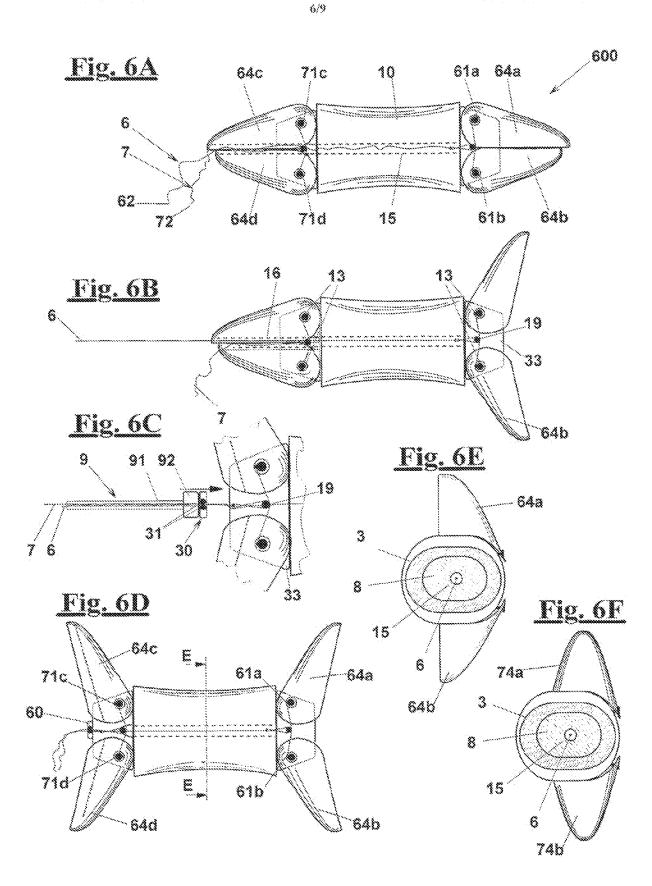


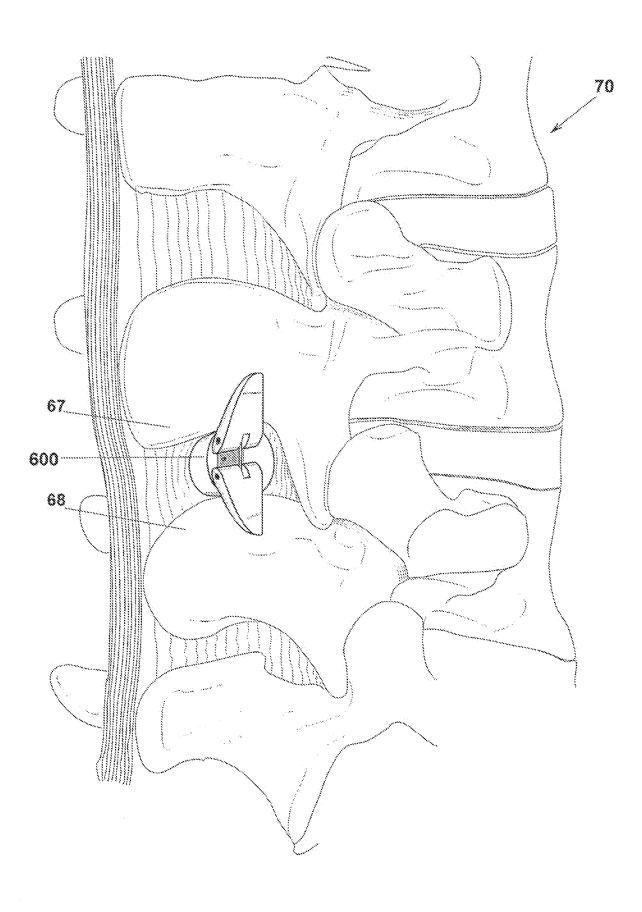


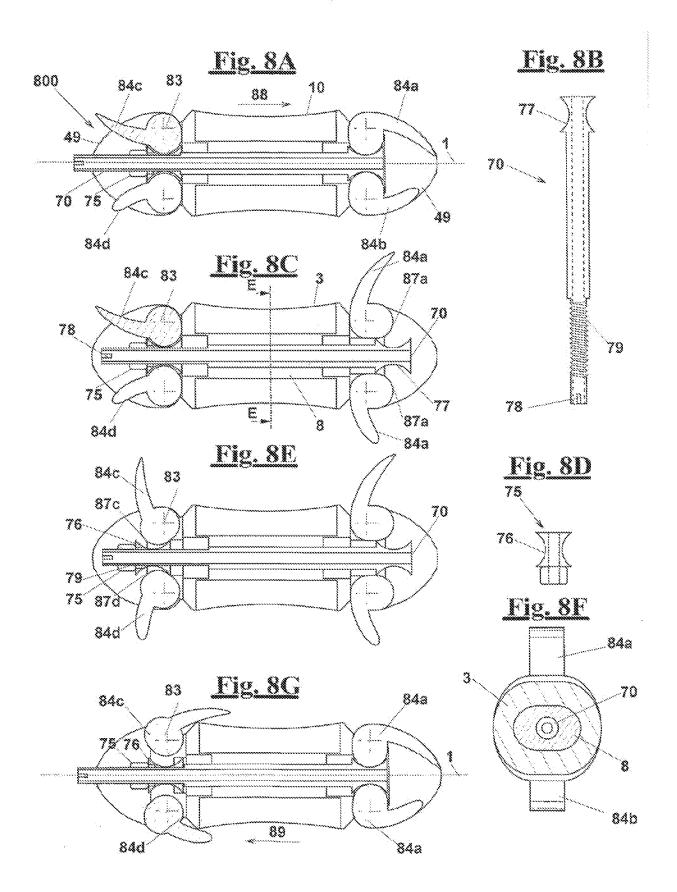


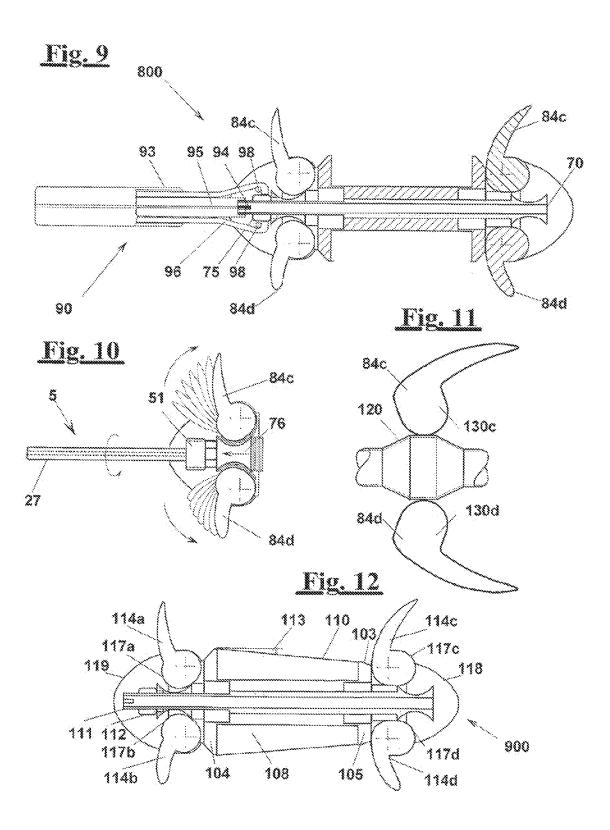












International application No PCT/IB2008/001344

a. Classification of subject matter INV. A61B17/70 A61B1 A61B17/88 According to International Patent Classification (IPC) or to both national classification and IPC 8. FIELOS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A618 Documentation searched other than minimum documentation to the extent that such documents are included, in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal C. DOCUMENTS CONSIDERED TO BE RELEVANT Category: Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 2007/075788 A (VERTIFLEX INC [US]; 1~4.6 ALTARAC MOTI [US]; TEBBE SHAWN [US]; FLAHERTY CHRI) 5 July 2007 (2007-07-05) page 6, paragraph 17 page 21, paragraph 109 - page 23, paragraph 112 page 24, paragraph 115 - page 25, paragraph 117 page 26, paragraph 119 - page 27, paragraph 121 page 30, paragraph 130 - page 31, paragraph 132 page 37, paragraph 150 - page 40, paragraph 157 figures 14A-14C.19A-198.2OA-208.21.25A-25C.32A-32C A 11,23,24 X Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: "T" later document published after the international flang date or priority date and not in conflict with the application but clied to understand the principle or theory underlying the "A" document defining the general state of the an which is not considered to be of particular relevance. negmen "E" earlier document but published on or after the international "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to tiling date *L* document which may throw doubts on priority claim(s) or which is clied to establish the publication date of another involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention citation or other special reason (as specified) cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document reterring to an oral disclosure, use, exhibition or ments, such combination being abvious to a person skilled in his art. other means document published prior to the international. Illing date but later than the priority date claimed "8" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 9 December 2008 17/12/2008 Name and mailing address of the ISA/ Authorized officer European Patem Office, P.S. 5818 Patentisan 2 NL - 2280 HV Rijskijk Tel (+31-70) 340-2040, Fax. (+31-70) 340-3016 Kakoullis, Marios

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INTERNATIONAL SEARCH REPORT

Box No. II Observations where cartain claims were found unsearchable (Continuation of item 2 of first sheet)
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: because they relate to parts of the infemational application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Output Decause they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box No. III Observations where unity of invention is tacking (Continuation of item 3 of first sheet)
This international Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
As all required additional search tees were timely paid by the applicant, this international search report covers alisearchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee. The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 23-25

1.1. claims: 1-9

Intervertebral distractor wherein said couple of said stabilizers that can rotate about said pivot point beyond said spread apart position continuing further for angles larger than 90° have a curved shape with concavity such that during the introduction it is oriented opposite to the axis of the body, and during the extraction it is oriented towards the axis of the body.

1.2. claims: 23~25

Intervertebral distractor wherein said means that can be operated percutaneously comprises a flexible tie member fixed to the stabilizers of at least one of said couples of stabilizers, such that such stabilizers are brought from the closed position to the spread apart position by pulling the tie member, means for blocking the flexible tie member when the stabilizers have achieved the spread apart position.

2. claim: 10

Intervertebral distractor wherein said stabilizers are enclosed laterally between fixed protection shells, said shells having a pointed profile such that resistance is reduced during an percutaneous introduction or extraction.

3. claims: 11-22

Intervertebral distractor wherein said means that can be operated percutaneously comprises a rod slidingly arranged in a longitudinal recess of the elongated body, said rod having at one end a cam-shaped portion adapted to be put in a space comprised within the stabilizers of the first couple,

such stabilizers having each a cam-shaped surface at said proximal end with respect to the body, adapted to engage with the cam-shaped portion of the rod such that a translation of the rod causes a rotation of the lateral stabilizers.

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